



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

7/22

DEC 23 1992

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PRODUCT CHEMISTRY REVIEW
EPA File Symbol 7078-RT

FROM: Treva C. Alston, Chemist
Product Chemistry Review Section
Registration Support Branch
Registration Division (H7505C)

TO: John Lee, Pm # 31
Anti-Microbial Branch
Registration Division (H7505C)

THRU: Donald Stubbs, Acting Section Chief
Product Chemistry Review Section
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Registration Division (H7505C)

Treva C. Alston

Requestor: Surgikos, Inc.

EPA File Symbol: 7078-RT

Pesticide Chemical Code: 129017

MRID #'s: 422417-00; 422799-01

CAS Registry #: 643-79-8

Chemical Name (Active Ingredient): 1,2-benzenedicarboxaldehyde ✓

Common/Trade Name: Ortho-phthalaldehyde/CIDEX, OPA Antimicrobial

Use: Antimicrobial

1



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Printed on paper that contains
at least 75% recycled fiber

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

Introduction: This submission is in response to agency letter of December 7, 1990 from product chemistry review of April 26, 1990 (Dynamac Corporation) for the new product registration of ortho-phthalaldehyde 99%T (EPA File Symbol 7078-RT). All product chemistry requirements pertaining to the technical grade of the active ingredient (TGAI) as described in 40 CFR 158.150 must be met to achieve full registration.

61-3: Discussion of the Formation of Impurities

See Confidential Appendix A. This section remains inadequate. The registrant must discuss quality control, post production reactions, and possible contamination from packaging materials.

62-1: Preliminary Analysis

Gas chromatographic analyses on five different lots of this TGAI have been provided. (See Appendix B for results.). This section remains inadequate for the following reasons. Complete and detailed descriptions of the methods used for sample analyses or a referenced method used must be submitted, including statements of their precision and accuracy.

62-2: Certified Limits

Confidential Statement of Formula was submitted. See appendix B for results.

Recommendations:

The product chemistry data requirements for pesticide registration for this TGAI have not been completely satisfied. The following product chemistry data requirements have to be fulfilled.

61-3: Discussion of the Formation of Impurities

The discussion must further provide quality control, post production reactions, and possible contamination from packaging materials.

62-1: Preliminary Analyses

Complete and detailed descriptions for the methods used or a referenced method used for sample analysis must be submitted, including statements of their precision and accuracy. The impurity, [REDACTED] identified on the CSF of March 6, 1992 is not indicated in the analysis of the TGAI.

Page is not included in this copy.

Pages 3 through 5 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
 - ☐ Identity of product impurities.
 - ☒ Description of the product manufacturing process.
 - ☐ Description of quality control procedures.
 - ☐ Identity of the source of product ingredients.
 - ☐ Sales or other commercial/financial information.
 - ☐ A draft product label.
 - ☐ The product confidential statement of formula.
 - ☐ Information about a pending registration action.
 - ☐ FIFRA registration data.
 - ☐ The document is a duplicate of page(s) .
 - ☐ The document is not responsive to the request.
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
